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April 16, 2004

Office of Nutritional Products, Labeling
and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Department of Health and Human Services
5100 Paint Branch Parkway, Building CPK1
College Park, Maryland 20740-3835



To Whom It May Concern:

Enclosed please find for filing a petition to permit the use of nutrient content claims for the carbohydrate content of food, submitted by Unilever United States, Inc. All correspondence on this petition should be sent to Unilever as stated in the petition.

We would like to request a meeting to discuss this petition with FDA, after you have had an opportunity to initially review it, preferably during the week of May 3rd. I will contact you to follow up on this request.

Thank you for your kind attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Daniel R. Dwyer".

Daniel R. Dwyer

Counsel to Unilever United States, Inc.

enclosure

2004P-0298

CP1



PETITION FOR NUTRIENT CONTENT CLAIMS

Name of Petitioner: Unilever United States, Inc.

Subject of Petition: Nutrient Content Claims for the Carbohydrate Content of Food

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April 16, 2004



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PETITION FOR NUTRIENT CONTENT CLAIMS

Name of Petitioner: Unilever United States, Inc.

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Subject of Petition: Nutrient Content Claims for the Carbohydrate Content of Food

Office of Nutritional Products, Labeling
and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Department of Health and Human Services
5100 Paint Branch Parkway, Building CPK1
College Park, Maryland 20740-3835

To Whom It May Concern:

Unilever United States, Inc. (Unilever), submits this petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) to request that the Food and Drug Administration (FDA) permit the use of nutrient content claims for the carbohydrate content of food.

EXECUTIVE SUMMARY

The goal of this petition is to provide for nutrient content claims about the carbohydrate content of food that can help consumers construct a healthy diet, particularly with respect to reducing the risk of overweight and obesity. To achieve this goal, the proposed claims distinguish between carbohydrates that contribute significant levels of calories to the diet (such as sugars and starches) and those that do not (such as dietary fiber and sugar alcohols). With these claims, consumers will be better able to reduce intake of the former types of carbohydrates without inadvertently also reducing intake of the latter types. Claims that fail to distinguish between these two types of carbohydrates would be

confusing and could cause consumers to reduce their intake of beneficial dietary fiber in their effort to reduce carbohydrate intake.

Two key points support this goal:

- On March 12, 2004, FDA called for urgent steps to address overweight and obesity as a major public health problem in the United States, including changes in food labeling to help consumers improve their diets in order to reduce the incidence of overweight and obesity.
- Recent statements of authoritative scientific bodies have affirmed that the critical factor in weight control is the intake of energy (calories). These statements provide a clear rationale for distinguishing between different types of carbohydrates (such as sugars and dietary fiber) based on their caloric contribution to the diet and consequent effect on the risk of weight gain.

To achieve this goal, the following claims are proposed:

“Carbohydrate Free” (and synonyms). “Carbohydrate free” (and synonyms) may be used on the labeling of a food that contains less than 0.5 g carbohydrate per reference amount customarily consumed (RACC) and per serving, *excluding* dietary fiber and the non-caloric proportion of sugar alcohols. (For meal and main dish products, these criteria must be met per serving.)

If the combined levels of dietary fiber and the non-caloric proportion of sugar alcohols in the food exceed 0.5 g per serving, then the claim must be accompanied by a statement such as, “Free of carbohydrates that provide calories (which excludes fiber and some sugar alcohols).” This statement must appear immediately adjacent to (or as part of) the claim.

“Low Carbohydrate” (and synonyms). “Low Carbohydrate” (and synonyms) may be used on the labeling of a food that contains less than 6 g carbohydrate per RACC, *excluding* dietary fiber and the non-caloric proportion of sugar alcohols. If the food has a RACC of 30 g or less or 2 tablespoons or less, then these criteria would also need to be met on a per-50-gram basis. For meals and main dish products, the “low” criteria would need to be met on a per-100-gram basis.

If the combined levels of dietary fiber and the non-caloric proportion of sugar alcohols in the food exceed 0.5 g per serving, then the claim must be accompanied by a statement such as, “Low in carbohydrates that provide calories (which excludes fiber and some sugar alcohols).” This statement must appear immediately adjacent to (or as part of) the claim or be linked to the claim by an asterisk.

“Reduced Carbohydrate” (and synonyms). “Reduced Carbohydrate” (and synonyms) may be used on the labeling of a food that contains at least 25% fewer carbohydrates per RACC (*excluding* fiber and the non-caloric proportion of sugar alcohols) than a reference food. For meals and main dish products, these criteria would need to be met on a per-100-gram basis.

If the combined levels of dietary fiber and the non-caloric proportion of sugar alcohols in the food exceed 0.5 g per serving, then the claim must be accompanied by a statement such as, “Reduced in carbohydrates that provide calories (which excludes fiber and some sugar alcohols).” This statement must appear immediately adjacent to (or as part of) the claim or be linked to the claim by an asterisk.

“Good Source” and “Excellent Source of Carbohydrates” (and synonyms). “Good Source” and “Excellent Source of Carbohydrates” (and synonyms) may be used on the labeling of a food that meets the following criteria:

- The food provides at least 22.5 g total carbohydrate per RACC for a “good source” or at least 45 g total carbohydrate per RACC for an “excellent source.”
- The food must contain no more than 25% of calories from sugars.
- The food must be at least a “good source” of dietary fiber (i.e., 2.5 g per RACC).

For meals and main dish products, these claims would be based on and refer to a specific food in the products.

The rationale for each of these claims is discussed in detail in section II below.

In addition, the petition proposes that, if a product is labeled as a food for special dietary use based on its carbohydrate content¹ but is not either “low” or “reduced” in calories or “low” or “reduced” in carbohydrates (as proposed by this petition), then the product must bear a statement such as, “See nutrition information for calorie content.”

The actions requested by this petition are consistent both with the best available science and with the public health goals of FDA’s recent “Calories Count” action plan to confront the Nation’s obesity problem. Because of the urgency of overweight and obesity as health problems, the requested claims should be authorized as soon as possible (in an Interim Final Rule).

¹ Label statements intended solely to identify products as foods for special dietary use are not subject to regulation as nutrient content claims, as discussed in section II.F.

I. ACTION REQUESTED

Unilever respectfully requests that, pursuant to section 403(r)(2) and (r)(4) of the Act and 21 CFR 101.69, FDA promulgate regulations permitting the use of the nutrient content claims for low levels of carbohydrate and relative claims described in sections II.B and II.C below, and the nutrient content claims for high levels of carbohydrate described in section II.D below. Because of the urgency of overweight and obesity as public health problems, Unilever further requests that FDA authorize such claims in an Interim Final Rule pursuant to section 403(r)(7) of the Act. A brief summary of the requested claims is provided below. The text of a proposed regulation is provided in Appendix A.

SUMMARY OF PROPOSED CLAIMS

CLAIM	PROPOSED CRITERIA
“Carbohydrate Free” (and synonyms)	<ul style="list-style-type: none"> • < 0.5 g carbs per RACC and per serving, excluding fiber and non-caloric proportion of sugar alcohols • For meals and main dishes: same criteria, per serving • If dietary fiber + the non-caloric proportion of sugar alcohols \geq 0.5g per serving, then label: “Free of carbohydrates that provide calories (which excludes fiber and some sugar alcohols).”
“Low Carbohydrate” (and synonyms)	<ul style="list-style-type: none"> • \leq 6 g carbs per RACC, excluding fiber and non-caloric proportion of sugar alcohols • Small serving size: per-50-g rule would apply • For meals and main dishes: same criteria, per 100 g • If dietary fiber + the non-caloric proportion of sugar alcohols \geq 0.5g per serving, then label: “Low in carbohydrates that provide calories (which excludes fiber and some sugar alcohols).”
“Reduced Carbohydrate” (and synonyms)	<ul style="list-style-type: none"> • \geq 25% less carbs per RACC than a reference food, excluding fiber and non-caloric proportion of sugar alcohols • For meals and main dishes: same criteria, per 100 g • If dietary fiber + the non-caloric proportion of sugar alcohols \geq 0.5g per serving, then label: “Reduced in carbohydrates that provide calories (which excludes fiber and some sugar alcohols).”
“Good Source of Carbohydrate” (and synonyms)	<ul style="list-style-type: none"> • \geq 22.5 g total carbs per RACC, \leq 25% of calories from sugar, and \geq 2.5 g per RACC of dietary fiber • For meals and main dishes: claim may be made for a food in the product
“Excellent Source of Carbohydrate” (and synonyms)	<ul style="list-style-type: none"> • \geq 45 g total carbs per RACC, \leq 25% of calories from sugar, and \geq 2.5 g per RACC of dietary fiber • For meals and main dishes: claim may be made for a food in the product

Other Requested Action

Statements on foods for special dietary use based on carbohydrate content	Foods for special dietary use based on carbohydrate content that are not either "low" or "reduced" in calories or "low" or "reduced" in carbohydrates must bear the disclosure statement, "See nutrition information for calorie content." (Label statements intended solely to identify products as foods for special dietary use are not subject to regulation as nutrient content claims, as discussed in section II.F.)
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II. STATEMENT OF GROUNDS

A. NEW INFORMATION SUPPORTS THE USE OF NUTRIENT CONTENT CLAIMS FOR CARBOHYDRATES

In 1993, when the Food and Drug Administration (FDA) published its final regulations governing nutrient content claims on food labels under section 403(r)(2) of the Act, it did not provide for nutrient content claims that used the term "carbohydrates."² The principal reason was that the available dietary guidance did not provide consistent recommendations about consumption of carbohydrates as a group. Although dietary guidance generally encouraged increased consumption of "complex carbohydrates" while suggesting that sugars intake be limited,³ there was not a consensus on how to define "complex carbohydrates."⁴

As a result, FDA concluded that nutrient content claims about "carbohydrates" (such as "high" or "source of") would provide misleading dietary advice. "At best," FDA said, such claims would be ambiguous in that they would not allow for the distinction between levels of complex carbohydrates and levels of sugars.⁵ In its final rule, FDA permitted claims only about some individual types of carbohydrates (such as "high fiber" and "reduced sugar").

² 21 CFR 101.54(a); 58 Fed. Reg. 2302, 2343, 2345 (comment 154), 2413 (Jan. 6, 1993).

³ 56 Fed. Reg. 60421, 60444 (Nov. 27, 1991).

⁴ 58 Fed. Reg. 2100.

⁵ 56 Fed. Reg. 60421, 60444.

Since 1993, three important categories of new information have been developed that provide a compelling basis for labeling foods with nutrient content claims about carbohydrates in order to help consumers construct a healthy diet – particularly with respect to reducing the risk of overweight and obesity. This new information addresses the issues raised by FDA in 1993 in that it provides a basis for claims that effectively distinguish between levels of complex carbohydrates (such as dietary fiber) and levels of sugars. These three categories of new information are:

1. *New Scientific Information About Carbohydrate Intake and Weight Control*

Recent publications of the National Academy of Sciences Institute of Medicine (IOM) and a joint expert consultation of the World Health Organization (WHO) and the UN Food and Agriculture Organization (FAO) have affirmed that the critical factor in weight control is the intake of energy (calories). In its 2002 Macronutrient Report, the IOM recommended balancing energy intake with energy expenditure in order to maintain appropriate body weight.⁶ The IOM's analysis focused on the caloric contribution of carbohydrates (and other macronutrients) as determining their effect on the risk of weight gain. As a result, the IOM's analysis provides a basis for distinguishing between different types of carbohydrates (such as sugars and dietary fiber) based on their caloric contribution.

Similarly, in 2003 the WHO/FAO Expert Consultation stated that “high intake of energy-dense foods promotes weight gain. ... Energy-dense foods tend to be high in fat ... sugars or starch ...” In contrast, “high intake of [non-starch polysaccharides] (dietary fiber) promotes weight loss.”⁷ Importantly, this distinction between sugars and starches on the one hand and dietary fiber on the other is primarily a *caloric* distinction: the energy value of sugars and starches is 4 calories per gram, whereas that of dietary fiber is significantly less.⁸ (In addition, the slower absorption of dietary fiber and other low-glycemic-index foods is associated with reduced total energy intake in the diet (as well as

⁶ Institute of Medicine (IOM), *Dietary Reference Intakes: Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* (2002) (“Macronutrient Report”) at 5-4. Copies of scientific literature referred to in this petition are provided at Appendix D.

⁷ Joint WHO/FAO Expert Consultation. *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 916 (2003) at 63-64.

⁸ IOM Macronutrient Report at 7-8.

other health benefits).⁹ Thus, the conclusion of the WHO/FAO Expert Consultation is fundamentally the same as that of the IOM: the caloric contribution of carbohydrates is the most important factor in determining their effect on the risk of weight gain.

2. FDA's New Action Plan on Reducing Overweight and Obesity

On March 12, 2004, FDA published an action plan to address overweight and obesity as a major public health problem in the United States.¹⁰ The recommendations in the report of FDA's Obesity Working Group ("FDA Obesity Report") provide a sound basis for making changes in food labeling and taking other steps to help consumers improve their diets in order to reduce the incidence of overweight and obesity.¹¹

Importantly, the FDA Obesity Report focuses on *calories*: it states that attention to caloric intake is one of two key elements of weight control (the other being caloric expenditure). The analysis is succinct: "To maintain a constant bodyweight over time, 'energy in' from food must equal 'energy out' as a result of resting metabolism plus physical activity."¹² Further, noting that carbohydrates are one of the three macronutrients in the diet that contribute importantly to caloric intake, FDA commits to initiating rulemaking to ensure consistent use of nutrient content claims about carbohydrates.¹³

3. New Authoritative Dietary Guidance on Recommended Carbohydrate Intake

Since 1993, authoritative dietary guidance on carbohydrate intake has been clarified and strengthened. In its 2002 Macronutrient Report, the IOM established an "acceptable macronutrient distribution range" (AMDR) for carbohydrate in the diet of 45 to 65

⁹ *Id.* at 6-37, 6-41 - 6-42. The glycemic index describes the rate and extent of carbohydrate absorption after ingestion of a food, expressed as the rate and extent to which a food contributes to increased blood glucose levels.

¹⁰ FDA, Counting Calories, Report of the Working Group on Obesity (March 12, 2004) ("FDA Obesity Report").

¹¹ *See*, FDA Obesity Report; 68 Fed. Reg. 58117, 58118 (October 8, 2003).

¹² FDA Obesity Report, section II.A (Scientific Principles).

¹³ FDA, Fact Sheet, Carbohydrates (March 12, 2004).

percent of total calories.¹⁴ This is equivalent to approximately 225 to 325 grams of carbohydrate per day based on a 2000 calorie daily diet. In 2003, the IOM issued its report on the use of dietary reference intakes in nutrition labeling (“Nutrition Labeling Report”).¹⁵ Here, the IOM recommended using the AMDR as the basis for nutrition labeling for carbohydrate content (and therefore – because nutrient content claims are derived from nutrition labeling – as the basis for nutrient content claims).

Importantly, the IOM’s recommendation focuses on the *caloric* contribution of carbohydrates as the basis for nutrient content claims. As noted above, the AMDR, which is the foundation for the IOM’s recommendations, reflects an acceptable intake in terms of percent of total calories.

4. Conclusion: This New Information Supports the Approach taken in this Petition

These three categories of new information (that is, new scientific information on carbohydrate intake and weight control, FDA’s new action plan on reducing overweight and obesity, and new authoritative dietary guidance on recommended carbohydrate intake) establish two critical points:

- ***First***, in order to provide useful information to consumers about how to make healthy dietary choices relating to weight control, it is necessary to distinguish between carbohydrates that contribute significant levels of calories to the diet (i.e., sugars and starches) and those that do not (such as dietary fiber). Nutrient content claims about carbohydrates must enable consumers to identify foods that help them reduce consumption of the former types of carbohydrates while maintaining (or increasing) healthy levels of consumption of the latter. Claims that fail to distinguish between these two general categories of carbohydrates would be confusing to consumers and could do more harm than good by causing consumers to inadvertently reduce intake of dietary fiber in their effort to reduce carbohydrate intake.
- ***Second***, nutrient content claims that are based on the caloric contribution of carbohydrates are consistent both with the best available science and also with the public health goals expressed in the FDA Obesity Report. Therefore, because of the urgency of overweight and obesity as public health problems, such claims

¹⁴ IOM Macronutrient Report at 11-27.

¹⁵ IOM, Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification (2003) (“IOM Nutrition Labeling Report”) at 95.

should be authorized as requested in this petition. Further, this should be done as soon as possible, in an Interim Final Rule pursuant to section 403(r)(7) of the Act.

In summary, information about the carbohydrate content of food can help consumers construct a healthy diet, particularly with respect to reducing the risk of overweight and obesity – but only if that information distinguishes between carbohydrates that contribute significant levels of calories to the diet and those that do not. Indeed, nutrient content claims about carbohydrates *must* convey this distinction in order to meet the objectives of the underlying statute.¹⁶ The goal of this petition is to provide for such nutrient content claims.

The following sections discuss in more detail how the IOM's recommendations form the basis for nutrient content claims that distinguish between carbohydrates based on their caloric value.

**B. THE IOM'S RECOMMENDATIONS FORM THE BASIS FOR
NUTRIENT CONTENT CLAIMS THAT DISTINGUISH BETWEEN
CARBOHYDRATES BASED ON CALORIC VALUE**

In order to achieve the goal of developing nutrient content claims that distinguish between carbohydrates that contribute significant levels of calories to the diet and those that do not, the first step is to determine the appropriate value for the recommended daily intake of carbohydrates (the Daily Value, or DV) in terms of caloric intake, and the second step is to determine the extent to which different types of carbohydrate in foods contribute to meeting the DV.

In this section, we address these two steps for claims about low levels of carbohydrates (such as “low” and “free”) and relative claims (such as “reduced”). Claims about high levels of carbohydrates are discussed in section II.D.

¹⁶ FDA stated the objectives of the Nutrition Labeling and Education Act of 1990 as: “(1) To make available nutrition information that can assist consumers in selecting foods that can lead to healthier diets, (2) to eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent with the terms defined by the Secretary, and (3) to encourage product innovation through the development and marketing of nutritionally improved foods.” 58 Fed. Reg. 2302 (January 6, 1993). Claims that distinguish between carbohydrates that contribute significant levels of calories to the diet and those that do not will foster each of these objectives, whereas claims that fail to make this distinction will frustrate them.

1. *The IOM Recommends a DV for Carbohydrate of 275 g Based on Caloric Contribution*

In its Macronutrient Report and Nutrition Labeling Report, the IOM provides a strong scientific basis for developing regulatory standards for nutrient content claims that distinguish between carbohydrates based on their caloric contribution to the diet. The Nutrition Labeling Report recommends using the AMDR as the basis for carbohydrate claims, stating that the AMDR represents "a range of intakes ... that is associated with reduced risk of chronic disease while providing adequate intakes of essential nutrients ... expressed as a percentage of total energy."¹⁷ The report explains:

To promote healthful dietary practices and nutritionally adequate diets and to provide consistency for setting label reference values for ... total carbohydrate ..., the committee believes that an approach based on the AMDR is most appropriate. ... The committee recommends using the midpoint of the AMDR for total carbohydrate (since the AMDR for carbohydrate is 45 to 65 percent of energy for all reference groups) * * * Using the midpoint of the AMDR as the basis for label reference values avoids extreme values (i.e., lower- or upper-boundary levels) and is an approach that focuses on moderation.¹⁸

Accordingly, an appropriate basis for claims about low levels of carbohydrates is the midpoint of the AMDR, i.e., 55 percent of total calories. The Nutrition Labeling Report further recommends that the DV expressed in labeling be based on a 2000 calorie daily diet. Thus, the DV for carbohydrate would be 1100 calories. Based on the standard conversion factor of 4 calories per gram of carbohydrate, the DV for carbohydrate by weight would be 275 g.

2. *Only Carbohydrates that Provide Significant Levels of Calories to the Diet Contribute to the DV*

Because the AMDR for carbohydrate is expressed as a percent of energy (calories), the 275 g DV for carbohydrate represents only the quantity of carbohydrates that contribute significant levels of calories to the diet. It *excludes* the quantity of carbohydrates that do not contribute significantly to such levels.

¹⁷ IOM Nutrition Labeling Report at 93 (*quoting* IOM, Dietary Reference Intakes: Applications in Dietary Assessment (2002) at S-5).

¹⁸ *Id.* at 95.

The vast majority of carbohydrates in the diet, consisting of sugars and starches, contribute caloric value at the 4 calorie-per-gram level on which the 275 g DV is based. Thus, each gram of sugars and starches in a food counts fully toward meeting the DV. Information on the levels of these carbohydrates in food is most relevant to consumers for purposes of reducing the risk of overweight and obesity.

The two principal types of carbohydrates that do not contribute significant levels of calories to the diet are dietary fiber and sugar alcohols. These carbohydrates cannot be counted as contributing to the DV in the same way as sugars and starches. The following paragraphs address the contribution to the DV of these two types of carbohydrates.

a. Dietary Fiber

The American Association of Cereal Chemists (AACC) defines fiber as “the edible parts of plants or analogous carbohydrates that are resistant to digestion and absorption in the human small intestine with complete or partial fermentation in the large intestine. Dietary fiber includes polysaccharides, oligosaccharides, lignin, and associated plant substances. Dietary fibers promote beneficial physiological effects including laxation, and/or blood cholesterol attenuation, and/or blood glucose attenuation.”¹⁹ Similarly, the IOM refers to “fiber” as including soluble and insoluble fiber (as defined in 21 CFR 101.9(c)(6)(i)), as well as additional carbohydrates that may be covered by FDA’s definition of “other carbohydrate” (21 CFR 101.9(c)(6)(iv)) (such as inulin and oligofructose).²⁰

However defined, the key aspect of dietary fiber is its resistance to digestion and absorption in the small intestine. It therefore does not contribute energy to the human body in the same manner as sugars and starches, which are readily digested and absorbed in the small intestine. Dietary fiber passes through the small intestine and, in the large intestine, is subject to fermentation by microflora. As a result of this process, fiber can contribute some caloric value, but the extent of the energy released and the extent to which it is used by the body as fuel for normal metabolic processes is not well known and may vary depending on the composition of the fiber, the food in which it is found, and the total diet; the extent to which energy is used by bacteria in the colon; differences in individual metabolism; and other factors. Although the IOM refers to data suggesting

¹⁹ Report of the Dietary Fiber Definition Committee to the Board of Directors of the American Association of Cereal Chemists. March 2001; *Cereal Foods World* 46(3):112-126.

²⁰ IOM Macronutrient Report at 7-8.

that fiber may contribute between 1.5 to 2.5 calories per gram, utilized by the body in limited ways, it notes that the actual caloric contribution of fiber is “still unclear.”²¹

In summary, fiber is not a meaningful source of energy. Rather, it has other extremely important and beneficial functions in the diet; some of these are noted in the AACC definition above and others are discussed in the IOM Macronutrient Report.²² In light of these beneficial functions, the consumption of dietary fiber should not be discouraged (which would result if fiber were grouped together with sugars and starches for purposes of nutrient content claims) but rather should be encouraged (by distinguishing fiber from sugars and starches).

For all of the reasons outlined above, it is reasonable to conclude that, for purposes of a nutrient content claim for carbohydrate, dietary fiber should not count as contributing to the 275 g DV for carbohydrate.

b. Sugar Alcohols

The IOM notes that sugar alcohols could be considered “functional fiber,” but they can be distinguished from fiber in that they are subject to different digestive processes than fiber and have different functional effects (in addition to the fact that they are labeled separately from fiber for purposes of food labeling). Unlike dietary fiber, sugar alcohols are partially digested and absorbed in the small intestine and the extent to which they contribute energy for normal metabolic processes is well known. The following summarizes the caloric value of the principal sugar alcohols:

- 0.2 calories per gram for erythritol;
- 1.6 for mannitol;
- 2.0 for isomalt
- 2.0 for lactitol;
- 2.1 for maltitol;
- 2.4 for xylitol;

²¹ *Id.*

²² Consumption of low-glycemic-index foods have been associated with reduced dietary caloric intake as compared with consumption of high-glycemic-index foods in short term studies. IOM Macronutrient Report at 6-37. The IOM has stated that, “at a time when populations are increasingly obese, inactive and prone to insulin resistance ... dietary interventions that reduce insulin demand may have advantages. In this section of the population, it is likely that more slowly absorbed carbohydrate foods and low glycemic load diets will have the greatest advantage” *Id.* at 6-41 - 6-42. See also the discussion of dietary fiber in chapter 7 of the IOM Macronutrient Report.

- 2.6 for sorbitol;
- 3.0 for hydrogenated starch hydrolysates; and
- 4.0 for glycerin.²³

In summary, sugar alcohols are, in general, not a significant source of energy, but they do contribute some energy to the diet. Indeed, the importance of sugar alcohols in the diet has increased over the past few years and is expected to increase further as these ingredients are substituted for higher calorie sweeteners in the formulation of reduced-calorie foods.²⁴ In addition, sugar alcohols are associated with the beneficial effects referred to above with respect to foods that are more slowly digested and absorbed.²⁵ Therefore, the consumption of sugar alcohols should not be discouraged (which would result if sugar alcohols were grouped together with sugars and starches for purposes of nutrient content claims) but rather should be encouraged (by distinguishing sugar alcohols from sugars and starches).

For these reasons, it is appropriate to conclude that, for purposes of a nutrient content claim for carbohydrate, only the caloric proportion of each sugar alcohol (as compared with the 4 calories per gram of sugars and starches) should count as contributing to the 275 g DV for carbohydrate. For example, isomalt provides about 2 calories per gram, as compared with 4 calories per gram provided by sugars and starches. Therefore, each gram of isomalt should count as contributing only ½-gram to the DV for carbohydrate. The following summarizes the caloric proportion of the contribution to the DV made by one gram of each of the above-referenced sugar alcohols:

- 0.05 g for erythritol;
- 0.4 g for mannitol;
- 0.5 g for isomalt
- 0.5 g for lactitol;
- 0.525 g for maltitol;
- 0.6 g for xylitol;

²³ American Dietetic Association. Position of the American Dietetic Association: Use of Nutritive and Nonnutritive Sweeteners. *J Am Dietetic Assoc.* 2004;104:255-275.

²⁴ The American Dietetic Association provides a summary of the safety and palatability of sugar alcohols in its position statement, which concludes that “consumers can safely enjoy a range of nutritive and nonnutritive sweeteners when consumed in a diet that is guided by current federal nutrition recommendations ... as well as individual health goals.” *Id.*

²⁵ See footnote 22.

- 0.65 g for sorbitol;
- 0.75 g for hydrogenated starch hydrolysates; and
- 1.0 g for glycerin.

In conclusion, the 275 g DV for carbohydrate includes only those carbohydrates that contribute significant levels of calories to the diet. Therefore, in order to determine whether a food is “free,” “low,” or “reduced” in carbohydrates, the level of carbohydrates in the food should be measured by *excluding* dietary fiber and the non-caloric proportion of sugar alcohols.²⁶ The following section sets forth the proposed criteria for each of these claims.

C. CRITERIA FOR NUTRIENT CONTENT CLAIMS ABOUT LOW AND REDUCED LEVELS OF CARBOHYDRATES ARE BASED ON FDA’S STANDARD DEFINITIONS FOR SUCH CLAIMS

In order to achieve the goal of developing nutrient content claims that distinguish between carbohydrates that contribute significant levels of calories to the diet and those that do not, it is requested that FDA approve the following criteria for claims about low levels of carbohydrates (such as “free” and “low”) and relative claims (such as “reduced”).²⁷ These criteria are based on the IOM’s recommendations (as discussed above) and on FDA’s standard definitions for such claims.

1. “Carbohydrate Free” (and synonyms)

FDA’s standard practice has been to provide that a food may be described as “free” of a nutrient if the level of the nutrient is at or near the reliable limit of detection and is

²⁶ The quantity of dietary fiber and sugar alcohols to be excluded from carbohydrates for purposes of the claims proposed by this petition would be measured consistently with 21 CFR 101.9(c)(6) and (g). If any substances that should be considered as fiber or sugar alcohols are not analyzed as such under these regulatory provisions (for example, inulin, oligofructose, and resistant starch, which should be considered as fiber), this issue will be addressed separately with FDA.

²⁷ Unless otherwise stated in this petition, the general conditions applicable to nutrient content claims under 21 CFR 101.13 would apply to nutrient content claims about carbohydrates. Examples of foods that may be eligible for claims about low and reduced levels of carbohydrates are provided at Appendix E.

dietetically trivial or physiologically inconsequential.²⁸ For carbohydrate, FDA has established that “0 g” may be declared if a serving contains less than 0.5 gram.²⁹ FDA’s practice has also been to require a “free” claim to be based on levels of the nutrient per RACC and per serving (except that claims for meal and main dish products are based on per-serving levels).³⁰

As discussed in section II.B above, this petition requests that nutrient content claims for carbohydrate be based on the level of carbohydrate in the food *excluding* dietary fiber and the non-caloric proportion of sugar alcohols, to ensure that the claim distinguishes between carbohydrates that contribute significant levels of calories to the diet (i.e., sugars and starches) and those that do not (such as fiber and sugar alcohols).

Accordingly, the claim “carbohydrate free” (and synonyms) may be made on the labeling of a food that contains less than 0.5 g carbohydrate per RACC and per serving, *excluding* dietary fiber and the non-caloric proportion of sugar alcohols.

If the combined levels of dietary fiber and the non-caloric proportion of sugar alcohols in the food exceed 0.5 g per serving, then, in order to ensure that consumers understand that the claim refers only to carbohydrates that contribute significantly to caloric value (and to ensure that the claim is consistent with the Nutrition Facts box), the claim must be accompanied by a statement disclosing the type of carbohydrates to which the claim refers, such as, “Free of carbohydrates that provide calories (which excludes fiber and some sugar alcohols).” This statement must appear immediately adjacent to (or as part of) the claim.

These same conditions would apply to meal type products³¹ and main dish products³² based on per-serving levels.

²⁸ 56 Fed. Reg. at 60433.

²⁹ 21 CFR 101.9(c)(6).

³⁰ See e.g., 21 CFR 101.62(b)(1)(i).

³¹ 21 CFR 101.13(l).

³² *Id.* at 101.13(m).

2. “Low in Carbohydrates” (and synonyms)

In the past, FDA’s standard practice with respect to “low” claims has been to set a “low” level on a per-RACC basis by multiplying the DV for a nutrient by a certain percentage. The percentage used depends on how common the nutrient is in the food supply. FDA typically uses 2 percent for “ubiquitous” nutrients (such as calories).³³

Carbohydrates that contribute significant caloric value to the diet are very common in the food supply. Although they are not found in every food category, they are found in the majority. For example, of 23 food categories identified in the USDA’s Nutrient Database for Standard Reference, carbohydrates can reasonably be expected to be found in significant quantities in approximately 17 categories.³⁴ For both men and women, carbohydrates make up about half of total dietary energy.³⁵ Thus, it is reasonable to conclude that caloric carbohydrates are ubiquitous in the diet.

Therefore, using a factor of 2 percent multiplied by the DV of 275 g established in section II.B above, a “low” level of carbohydrate is 5.5 g, which can be rounded up to 6 g per RACC.

As discussed in section II.B above, this petition requests that nutrient content claims for carbohydrate be based on the level of carbohydrates in the food *excluding* dietary fiber and the non-caloric proportion of sugar alcohols, to ensure that the claim distinguishes between carbohydrates that contribute significant levels of calories to the diet (i.e., sugars and starches) and those that do not (such as fiber and sugar alcohols).

³³ 56 Fed. Reg. 60439-60441.

³⁴ The 23 categories are: (1) Dairy and Egg Products; (2) Spices and Herbs; (3) Baby Foods; (4) Fats and Oils; (5) Poultry Products; (6) Soups, Sauces, and Gravies; (7) Sausages and Luncheon Meats; (8) Breakfast Cereals; (9) Fruits and Fruit Juices; (10) Pork Products; (11) Vegetables and Vegetable Products; (12) Nut and Seed Products; (13) Beef Products; (14) Beverages; (15) Finfish and Shellfish Products; (16) Legumes and Legume Products; (17) Lamb, Veal, and Game Products; (18) Baked Products; (19) Sweets; (20) Cereal Grains and Pasta; (21) Fast Foods; (22) Meals, Entrees, and Sidedishes; and (23) Snacks. See <http://www.nal.usda.gov/fnic/foodcomp/Data/SR16-1/reports/sr16-1pg.htm>.

³⁵ IOM Macronutrient Report, App. E.

Accordingly, the claim “low in carbohydrates” (and synonyms) may be made on the labeling of a food that contains less than 6 g carbohydrate per RACC, *excluding* dietary fiber and the non-caloric proportion of sugar alcohols.

In order to prevent nutrient-dense foods with small serving sizes from making “low” claims, FDA’s standard approach is to require foods with a RACC of 30 g or less or 2 tablespoons or less also to meet the “low” criteria on a per-50-gram basis. (*See e.g.*, 21 CFR 101.62(b)(2)(i)(B).) This same approach should apply to the claim “low in carbohydrates.”

If the combined levels of dietary fiber and the non-caloric proportion of sugar alcohols in the food exceed 0.5 g per serving, then, in order to ensure that consumers understand that the claim refers only to carbohydrates that contribute significantly to caloric value (and to ensure that the claim is consistent with the Nutrition Facts box), the claim must be accompanied by a statement disclosing the type of carbohydrates to which the claim refers, such as, “Low in carbohydrates that provide calories (which excludes fiber and some sugar alcohols).” This statement must either appear immediately adjacent to (or as part of) the claim or be linked to the claim by an asterisk.³⁶

FDA typically defines “low” nutrient content claims for meal type products and main dish products on a per-100-gram basis, rather than the per-RACC-basis used for individual foods.³⁷ This same approach would apply to “low carbohydrate” claims for meals and main dishes.

The proposed definition for “low” carbohydrate is consistent with the current dietary recommendations for carbohydrate in the IOM Macronutrient Report. In its report, the IOM established an estimated average requirement (EAR) for carbohydrate based on an amount of digestible carbohydrate that would provide the central nervous system with an adequate supply of glucose fuel. The EAR for children age 1 and older, and for adults, is 100 g per day. The IOM also established a recommended dietary allowance (RDA), consisting of the EAR plus twice the coefficient of variation based on brain glucose utilization, to cover the needs of 97 to 98 percent of individuals. The RDA for children age 1 and older, and for adults, is 130 g per day. Although these levels are considered adequate, the IOM noted that the brain can still receive enough glucose from the

³⁶ The proposed qualifying information need not appear immediately adjacent to the “low carbohydrate” claim in order for the claim to be adequately understood by consumers. At this time carbohydrate claims are common in the marketplace and consumers expect them to bear some relationship to the caloric content of food and/or the ability to use the food as part of an overall diet for weight control.

³⁷ 58 Fed. Reg. at 2379.

metabolism of the glycerol component of fat and from the gluconeogenic amino acids in protein when consuming a diet that is very low in carbohydrate.³⁸ Further, as discussed in section II.B.1 above, the IOM established an AMDR that results in a DV for carbohydrate of 275 g.

Assuming consumption of 16 to 20 servings of foods and beverages per day, persons consuming only “low carbohydrate” foods would consume approximately 96 to 120 g caloric carbohydrates per day. This would be consistent with the IOM’s EAR and very close to the RDA, and would provide 35 to 44 percent of the 275 g DV. Thus, such consumption would provide adequate carbohydrate intake while still permitting a meaningful reduction in carbohydrates as compared with the DV. Importantly, in evaluating the adequacy of such intake, it is important to note that (1) it would be unusual for all foods in the diet to be “low” in carbohydrate over a long term, and (2) intake of other macronutrients can compensate for deficiencies in carbohydrate intake, if necessary.

3. Relative Claims (“Reduced,” “Fewer,” and synonyms)

FDA regulations provide that “A food may bear a statement that compares the level of a nutrient in the food with the level of a nutrient in a reference food.” Approved descriptors for such “relative claims” include: “reduced,” “fewer,” and “less.”³⁹ To ensure that relative claims represent a nutritionally significant difference in nutrient content, FDA’s standard practice has been to require a minimum percentage reduction of 25 percent for use of “reduced,” “fewer,” and “less” claims.⁴⁰

As discussed in section II.B above, this petition requests that nutrient content claims for carbohydrate be based on the level of carbohydrates in the food *excluding* dietary fiber and the non-caloric proportion of sugar alcohols, to ensure that the claim distinguishes between carbohydrates that contribute significant levels of calories to the diet (i.e., sugars and starches) and those that do not (such as fiber and sugar alcohols).

Accordingly, the claim “reduced in carbohydrates” (and synonyms) may be made on the labeling of a food that contains at least 25 percent less carbohydrate per RACC than an appropriate reference food, *excluding* dietary fiber and the non-caloric proportion of sugar alcohols. (That is, the calculation of the 25 percent reduction is based on a

³⁸ IOM Macronutrient Report at 6-15 – 6-19.

³⁹ 21 CFR 101.13(j).

⁴⁰ See e.g. 21 CFR 101.62(b)(4)(i) (“reduced fat”).

comparison of carbohydrates that exclude dietary fiber and the non-caloric proportion of sugar alcohols.)

If the combined levels of dietary fiber and the non-caloric proportion of sugar alcohols in the food exceed 0.5 g per serving, then, in order to ensure that consumers understand that the claim refers only to carbohydrates that contribute significantly to caloric value (and to ensure that the claim is consistent with the Nutrition Facts box), the claim must be accompanied by a statement disclosing the type of carbohydrates to which the claim refers, such as, "Reduced in carbohydrates that provide calories (which excludes fiber and some sugar alcohols)." This statement must either appear immediately adjacent to (or as part of) the claim or be linked to the claim by an asterisk.⁴¹

Other standard conditions for relative claims would apply to claims about carbohydrates, consistent with, for example, 21 CFR 101.62(b)(4)(ii) and (iii).

FDA typically defines relative nutrient content claims for meal type products and main dish products on a per-100-gram basis, rather than the per-RACC basis used for individual foods.⁴² This same approach would apply to relative claims for carbohydrates.

D. CRITERIA FOR NUTRIENT CONTENT CLAIMS ABOUT HIGH LEVELS OF CARBOHYDRATES ARE BASED ON FDA'S STANDARD DEFINITIONS FOR SUCH CLAIMS

It is requested that FDA approve nutrient content claims for "good source" and "excellent source" of carbohydrates (and synonyms), the criteria for which are based on the IOM's recommendations and on FDA's standard definitions for such claims.⁴³

As discussed in section II.A above, consumers need useful information about how to make healthy dietary choices relating to weight control. This includes not only

⁴¹ The proposed qualifying information need not appear immediately adjacent to the "reduced carbohydrate" claim in order for the claim to be adequately understood by consumers. At this time carbohydrate claims are common in the marketplace and consumers expect them to bear some relationship to the caloric content of food and/or the ability to use the food as part of an overall diet for weight control.

⁴² See e.g., 21 CFR 101.62(b)(5).

⁴³ Unless otherwise indicated in this petition, the general conditions applicable to such claims under 21 CFR 101.54 would apply to nutrient content claims about carbohydrates. Examples of foods that may be eligible for claims about high levels of carbohydrates are provided at Appendix E.

information to assist in reducing intake of carbohydrates that contribute significant levels of calories to the diet (as would be provided by the proposed claims “free,” “low,” and “reduced”), but also information to assist in maintaining or increasing intake of total carbohydrates including carbohydrates that do not contribute significantly to caloric value (such as dietary fiber and sugar alcohols). As discussed above, dietary fiber is associated not only with an insignificant caloric value but also with well-established health benefits. From the perspective of maintaining overall good health and reducing the risk of overweight and obesity, it is particularly important for consumers to obtain adequate intake of dietary fiber while at the same time avoiding excessive intake of sugar. It is appropriate for FDA to authorize the use of “good source” and “excellent source” claims for carbohydrates on the labeling of foods in which total carbohydrates include significant levels of dietary fiber and exclude significant levels of sugar.

Accordingly, in order to identify foods that are a “good source” and “excellent source” of carbohydrates, the following approach is proposed:

- The claim should be based on the low end of the AMDR, i.e., 45% of calories from carbohydrate, equivalent to 900 calories per day or 225 g per day. The low end is selected (rather than the midpoint, as used for “low” and “reduced” claims) because a food that contributes significantly to achieving this minimum recommended level should be eligible to be identified as a “good” or “excellent” source of carbohydrate.
- Using the standard FDA factors of 10 percent for “good source” and 20 percent for “excellent source,”⁴⁴ the respective carbohydrate levels would be 22.5 g and 45 g per RACC. Any type of carbohydrate (i.e., starches, sugars, sugar alcohols, and/or dietary fiber) may contribute to meeting these levels.
- To ensure that “good source” and “excellent source” foods provide a healthy balance of carbohydrates, two additional criteria must be met:
 - The food must contain no more than 25 percent of calories from sugars (based generally on the IOM’s suggestion that maximum intake from added sugars be 25 percent); and
 - The food must be at least a “good source” of dietary fiber (i.e., 2.5 g per RACC).

⁴⁴ 21 CFR 101.54(b), (c).

FDA's existing practice of requiring "good source" and "excellent source" claims on meals and main dish products to be based on, and refer to, a specific food,⁴⁵ would also apply to claims for carbohydrate.

E. THE PROPOSED NUTRIENT CONTENT CLAIMS ARE SUPPORTED BY INDEPENDENT EXPERTS

This petition is supported by two independent experts who are qualified by scientific training and experience to evaluate the usefulness of claims about the carbohydrate content of food in helping consumers construct a healthy diet, particularly with respect to reducing the risk of overweight and obesity. These experts are:

- Robert H. Eckel, M.D.
Charles A. Boettcher Endowed Chair in Atherosclerosis
Professor of Medicine and of Physiology and Biophysics
Program Director, Adult General Clinical Research Center
University of Colorado
- Ernst J. Schaefer, M.D.
Professor of Medicine
Chief, Lipid Research Laboratory
Director, Lipid and Heart Disease Research Program
Tufts University

Dr. Eckel concludes that "nutrient content claims about carbohydrates will assist consumers in maintaining healthy dietary practices, but only so long as they distinguish between carbohydrates that contribute significant levels of calories to the diet and those that do not. Unilever's petition would provide for such claims, and I therefore urge FDA to adopt the claims that it proposes."

Dr. Schaefer concludes, "I fully support Unilever's petition as being scientifically sound and nutritionally responsible. Most importantly, it would permit claims that are genuinely useful to consumers, and therefore would provide an important benefit to consumers as they seek to maintain healthy dietary practices."

Copies of letters from Drs. Eckel and Schaefer are provided at Appendix B, and copies of their curricula vitae are provided at Appendix C.

⁴⁵ 21 CFR 101.54(b)(2), (c)(2).

F. STATEMENTS INTENDED SOLELY TO IDENTIFY PRODUCTS AS FOODS FOR SPECIAL DIETARY USE ARE NOT SUBJECT TO REGULATION AS NUTRIENT CONTENT CLAIMS, BUT LABELING FOR SUCH PRODUCTS SHOULD NOT BE CONFUSING WITH RESPECT TO CALORIE CONTENT

This petition is intended to provide for the use of nutrient content claims about carbohydrates that will provide simple, reliable information that consumers can easily use to identify foods that will help them construct a healthy diet – particularly with respect to reducing the risk of overweight and obesity. This goal will be fostered by using claims that are consistently defined and enforced by FDA.

Importantly, the scope of nutrient content claims is limited and not all claims that refer to “carbohydrates” would be subject to regulation as nutrient content claims. In particular, certain claims that identify foods for special dietary use would not be subject to regulation as nutrient content claims.

A nutrient content claim is a claim that “expressly or implicitly characterizes the level of a nutrient.”⁴⁶ A label statement is generally not an implied nutrient content claim if it is made solely to note that a food has special dietary usefulness, where the claim identifies the special diet in which the food is intended to be a part and is made in compliance with a specific provision of 21 CFR Part 105, which governs “foods for special dietary use.”⁴⁷ A food is considered to be “for special dietary use” if it is for particular (as distinguished from general) use “for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of ... overweight.” This definition of “special dietary use” has been in effect under FDA regulations since 1941⁴⁸ and remains unchanged in current 21 CFR 105.3(a)(1).⁴⁹

⁴⁶ 21 CFR 101.13(b); *see also* section 403(r)(1)(A) of the Act.

⁴⁷ 21 CFR 101.65(b)(6).

⁴⁸ 6 Fed. Reg. 5921 (Nov. 22, 1941).

⁴⁹ There is also a statutory definition of “special dietary use” which was added in 1976 as 21 USC 350(c)(3). This definition is, in general, consistent with the regulation, as FDA explained at 61 Fed. Reg. 60661, 60662 (Nov. 29, 1996), section I. As FDA stated, the distinguishing characteristic of foods for special dietary use is that they are intended for use “by people with special dietary needs or desires....” (61 Fed. Reg. 60661, 60668, section III.D.)

Specific provisions of 21 CFR Part 105 provide that a food may be represented for special dietary use in reducing or maintaining body weight if: (1) it bears nutrition labeling, (2) it bears a conspicuous statement of the basis upon which the food claims to be of special dietary usefulness, (3) if applicable, it bears a statement that it contains a nonnutritive sweetener, and (4) any claims that suggest usefulness as low-calorie or reduced-calorie foods must be accompanied by "low-calorie," "reduced-calorie," or other similar claims (except for formulated meal replacements).⁵⁰

FDA has indicated that, by itself, a statement about dietary use by people with special dietary needs or desires would not be considered a nutrient content claim. For example, FDA has said:

- "A claim such as 'use as part of a weight reduction program' in and of itself, would not be considered to be a nutrient content claim."⁵¹
- "[I]n general, [FDA] would regard a brand name such as 'Weight Watchers,' when accompanied by information on the product label that suggests that the product can be useful in an overall weight-control diet plan, without any other reference to nutrient aspects of the food relative to the general population, to be a claim that solely portrays the usefulness of the food for a special dietary need as described in part 105."⁵²
- "A claim made solely to identify a food that meets a particular dietary need that exists by reason of a physical, physiological, pathological, or other condition as described in part 105 would generally not be a nutrient content claim (101.65(b)(6)). Thus, a claim such as 'Use as part of a weight reduction program' that identifies the special diet of which the food is intended to be a part would not, by itself, be a nutrient content claim."⁵³

⁵⁰ 21 CFR 105.66. In the 1993 preamble to 21 CFR 105.66, FDA explained that it is possible to market a food useful for weight control on a basis other than the food being low or reduced calorie, and that statements incorporating the term "diet" do not trigger the low calorie/reduced calorie requirements of 105.66(e) when they are used in a manner that does not suggest that the food is a low or reduced calorie food. 58 Fed. Reg. 2427, 2428-9 (comment 2).

⁵¹ 58 Fed. Reg. 2302, 2370 (comment 225).

⁵² 58 Fed. Reg. 2427, 2429 (comment 3).

⁵³ FDA, Food Labeling Questions and Answers: Vol. II, Feb. 1996 (#R115).

FDA affirmed this approach – and specifically discussed the applicability of this approach to claims about low-carbohydrate diets – in a 2002 letter to the Florida Department of Agriculture. In that letter, FDA said: “We also recognize that there may be ways for a product to bear a low carbohydrate lifestyle claim or a claim of usefulness in a carbohydrate-restricted diet without the claim being considered a nutrient content claim. The latter would be consistent with past positions that claims regarding the usefulness of a food as part of a weight reduction program and claims of value in sodium-restricted diets are not nutrient content claims.”⁵⁴

Accordingly, a claim that identifies a product as a food for special dietary use based on its carbohydrate content would, by itself, be consistent with FDA’s past practice that claims regarding the usefulness of a food as part of a weight reduction program are not nutrient content claims.

However, it is possible that a food labeled for special dietary use based on its carbohydrate content could be confusing to consumers who are interested in weight control if the product is not either “low” or “reduced” in calories, or “low” or “reduced” in carbohydrates (as defined in this petition). To reduce the risk of such confusion, this petition proposes that such a food bear a statement (in close proximity to the statement of special dietary use) such as, “See nutrition information for calorie content.”

G. CONCLUSION

The goal of this petition is to provide for nutrient content claims about the carbohydrate content of food that can help consumers construct a healthy diet, particularly with respect to reducing the risk of overweight and obesity. To achieve this goal, the proposed claims for low and reduced levels of carbohydrates distinguish between carbohydrates that contribute significant levels of calories to the diet (such as sugars and starches) and those that do not (such as fiber and sugar alcohols). As a result, consumers will be better able to reduce intake of the former types of carbohydrates without inadvertently also reducing intake of the latter types. Claims that fail to distinguish between these two general categories of carbohydrates would be confusing to consumers and could result in inappropriately reduced intake, particularly of dietary fiber.

This proposed approach to carbohydrate claims allows – and indeed encourages – reduction of caloric intake while still maintaining healthy consumption of a variety of carbohydrates. In particular, diets emphasizing “free,” “low,” and “reduced” carbohydrate foods could still contain abundant dietary fiber. Therefore, this petition is consistent with the IOM recommendation that “food selections emphasize grains, fruits,

⁵⁴ FDA letter to Florida Department of Agriculture (July 18, 2002).

and vegetables prepared with minimal or modest amounts of fat as the foundation of a healthful diet.”⁵⁵

Accordingly, the information presented in this petition is consistent with the requirements of section 403(r)(2) and (r)(4) and 21 CFR 101.69 in that it provides information adequate to establish that the requested nutrient content claims for carbohydrates would assist consumers in maintaining healthy dietary practices. Unilever respectfully requests that FDA approve the use of the nutrient content claims for low levels of carbohydrate and relative claims described in sections II.B and II.C above and the nutrient content claims for high levels of carbohydrate described in section II.D above. The text of a proposed regulation is provided in Appendix A.

We note that the authority granted to FDA under section 403(r) of the Act to promulgate regulations for nutrient content claims should be read consistently with the First Amendment of the U.S. Constitution. Under the First Amendment, a claim about the level of carbohydrates in a food is commercial speech that may not be lawfully restricted by FDA so long as the claim is not false or misleading. If a claim is scientifically valid and assists consumers in maintaining healthy dietary practices, then there is no substantial government interest in restricting such a claim. Any FDA regulation governing nutrient content claims for carbohydrates must not be so extensive as to ban truthful and non-misleading claims about carbohydrates that may assist consumers in building a healthful diet. Rather, FDA should formulate regulatory policy in a manner that is sufficiently flexible to permit a variety of truthful and non-misleading claims.

Unilever welcomes the opportunity to work cooperatively with the agency to provide food labeling information that will assist consumers in maintaining healthy dietary practices.

III. CLAIM FOR CATEGORICAL EXCLUSION

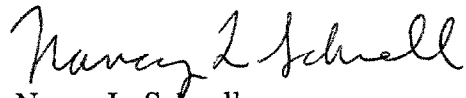
The action requested in this petition will have no significant effect on the quality of the human environment. The requested actions are among those subject to categorical exclusion provided in 21 CFR 25.32(p). Petitioner has no knowledge of extraordinary circumstances related to this request.

⁵⁵ IOM Macronutrient Report at 13-17. We are unaware of any basis for concluding that the claims proposed in this petition would result in significant increases in intake of fat, saturated fat, cholesterol or sodium. Indeed, such claims would assist consumers in regulating their intake of these nutrients because they would be accompanied by a referral statement alerting consumers to the presence of any significant levels of such nutrients.

IV. CERTIFICATION

Unilever certifies that, to its best knowledge and belief, this petition is a representative and balanced submission that includes unfavorable information as well as favorable information known to be pertinent to the evaluation of the petition.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Nancy L. Schnell".

Nancy L. Schnell
Deputy General Counsel –
Marketing and Regulatory